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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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3762	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,881	SKWAREK ET AL.	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-11,18-22,24,25 and 27-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-11,18-22,24,25 and 27-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 August 2007 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3, 5-11, 18, 24, 26, 30, 32 and 38 stand, and **claims 40 and 41 are, provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-11, 14-16, 22-28, 33-37, 40, 53, 56-58, 61-62, 65-67, 70-73, 78-82, 85-89, and 99-102 of copending Application No. 10/441,784. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications disclose a method and device with one or more leads for the delivery of one or more therapeutic stimulation pulses or sequences to tissue via an implantable medical device for the purpose of treating sexual dysfunction, where the stimuli might be delivered in response to telemetry signals from a patient programmer or in response to a sensed physiological signal, and might also be delivered in conjunction with a drug.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 30-32 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Krakovsky et al. (US Patent 5,454,840, hereinafter referred to as Krakovsky'840).

Regarding claims 30-32 and 38-40, Krakovsky'840 discloses an implantable/implanted medical device (potency package 30) comprising one or more electrode leads (Fig. 10, leads 48 and 49) capable of implantation within cellular muscle tissue of the prostate gland; a pulse generator (46), an optional agent pump (the implantable drug pump consisting of chamber 60, pump 62, and delivery tube 64) and a processor (42) to control the therapy delivery circuit; wherein the device is capable of delivering stimulation pulses and agents in a complimentary fashion causing the fiber structure of the prostate gland to relax, given these programmed parameters.

It is noted that the functional language of the device claims does not distinguish the instant application over the Krakovsky'840 device because the earlier patented device is inherently capable of all the limitations contained in the instant claims.

6. Claims 1, 4-11, 18, 30-32 and 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerber et al. (US 2004/0049240, hereinafter Gerber'240).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1. 5-9, 30 and 38, Gerber'240 discloses a method and system for providing medical therapy to a patient to treat sexual dysfunction (title: abstract) comprising delivering one or more stimulation pulses using electrodes implanted on or within the cellular muscle tissue of the prostate gland (abstract; paragraphs [44], [45], [47]) by one of causing or preventing erection or ejaculation, preventing premature ejaculation, and causing erection while preventing premature ejaculation (paragraph [5]).

Regarding claim 4, Gerber'240 shows the claimed ranges in Table 2 on page 6.

Regarding claim 10, Gerber'240 discloses a patient programmer (paragraphs [35], [37]).

Regarding claim 11, Gerber'240 discloses delivering therapy in response to sensed physiological conditions (paragraph [41]; claim 28).

Regarding claims 18, 31, 32 and 39, and further regarding claims 30 and 38, Gerber'240 discloses delivering drugs in conjunction with the stimulation pulses (paragraphs [50], [51]). It is noted that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding claim 40, Gerber'240 discloses simultaneous stimulation (paragraph [26]).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1, 5-11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky'840 in view of Whitehurst'294 or in view of Brenman et al. (US 4,663,102, hereinafter Brenman'102).

Regarding claims 1, 2, 5-10 and 18, Krakovsky'840 discloses the method substantially as claimed, including delivering one or more therapeutic stimulation pulses (Fig. 11) via an implantable medical device (potency package 30) to treat sexual dysfunction in which the stimulation can cause an erection and either cause (Fig. 13) or prevent (Fig. 12) ejaculation (column 1, lines 42-53) or premature ejaculation (column 5, lines 32-33); the stimulation being delivered in response to telemetry signals from a patient programmer (column 1, lines 36-38, 44-45), the second pulse train including more pulses per unit time (is of higher frequency) than the first pulse train (Figs. 12-13); the disclosed method also comprising delivering drugs to the prostate in conjunction with delivering electrical stimulation pulses (column 4, lines 28-54). Krakovsky'840 does not disclose that the stimulation pulses are delivered directly to the muscle tissue of the prostate. However, in the same field of endeavor, Whitehurst'294 teaches direct electrical stimulation of the prostate to provide a minimally invasive means of reducing prostate volume (column 3, lines 55-68). Additionally, Brenman'102 teaches direct electrical stimulation of the prostate gland to induce erection (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Krakovsky'840 to include direct electrical stimulation of the prostate gland as taught by Whitehurst'294 in order to provide the same benefit of

reducing prostate volume with a minimally invasive process (motivation to combine provided by Whitehurst'294, column 3, lines 55-68) or as taught in Brenman'102 to induce erection.

Regarding claim 11, Krakovsky'840 discloses the method of the instant application substantially as claimed except that the therapeutic stimulation pulses may be delivered in response to a sensed physiological condition. Whitehurst'294 teaches sensing necrosis, volume or inflammation of tissue as well as hormone, enzyme, or drug levels and changes as a means to determine the strength, duration, and pattern of electrical stimulation required to produce the desired treatment effect (column 11, lines 35-59).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a sensor for sensing physiological conditions into the device and method of the Krakovsky et al. patent for the same advantage of an alternate or more accurate means for determining the proper therapy levels to be delivered to the patient (motivation to combine provided by Krakovsky et al., column 11, lines 35-59).

10. Claims 19-22 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky'840 in view of Whitehurst'294 or in view of Brenman'102, and further in view of Mann et al. (US Patent 6,941,171, hereinafter referred to as Mann'171).

Krakovsky'840 in view of Whitehurst'294 or in view of Brenman'102 discloses the method of the instant application substantially as claimed except that the therapeutic

stimulation pulses be used to train the prostate gland to become more compliant, i.e. relax its fiber structure. In the same field of endeavor, Mann'171 teaches a stimulation of the nerve pathways of the bladder that yields the desired result of diminishing involuntary bladder contractions (i.e. relaxing the fibrous muscle structure of the bladder) and increasing volume of the bladder (i.e. increasing compliance of the bladder wall) (ABSTRACT).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that similar stimulation of the prostate, given its similar physical composition to the bladder and its corollary position in the reproductive system to that of the bladder in the urinary system, could be employed in the method of the Krakovsky'840 patent to achieve the same results of a relaxing of the fiber structure and increase in compliance of the prostate organ (motivation to combine provided by Mann'171, ABSTRACT).

See Figs. 12 and 13 of Krakovsky'840 regarding claims 34-37.

Further, Krakovsky'840 does not disclose that the time periods for the first and second pulse trains are on an order of a week. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a training period on the order of a week, since it has been held that, where the general conditions of a claim are disclosed in the prior art, discovering an optimum value or range for a result effective variable involves only routine skill in the art.

11. Claims 4 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky'840 in view of Whitehurst'294 or in view of Brenman'102 as applied to claims 1 and 19 above, and further in view of Mann'171.

Krakovsky'840 discloses the method of the instant application substantially as claimed except for the parameter limitations of using pulse widths between 180 and 450 microseconds and frequencies between 50 and 100 Hz (claim 4) or 2 and 20 Hz (claim 21). In the same field of endeavor, Mann'171 teaches a pulse width range of 50-350 microseconds and a frequency range of 2-20 pulses per second (Hz) as being typical for electrical stimulation of male reproductive nerves (column 21, line 48 through column 22, line 14).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ these ranges for stimulation parameters in the method of the Krakovsky'840 to achieve the same advantage of successful and clinically safe control of male sexual function (motivation to combine provided by Mann'171, column 21, line 48 through column 22, line 14).

12. Claims 24, 25, 27-29, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky'840.

Regarding claims 24, 25, 27-29, 41 and 42, Krakovsky'840 discloses an implantable medical device (potency package 30) comprising one or more leads (Fig. 10, leads 48 and 49), a pulse generator (46), an optional agent pump (the implantable drug pump consisting of chamber 60, pump 62, and delivery tube 64) and a processor (42) to control the therapy delivery circuit; wherein the second pulse train includes more

pulses per unit time than the first pulse train (Figs. 12 and 13); wherein the device defines pulses with amplitudes less than 10.5 volts and frequencies between 2 and 20 Hz, and is capable of pulse widths between 10 and 500 microseconds and pulse intervals of 10 to 500 milliseconds (Fig. 12, column 3, lines 36-46); wherein the device is capable of causing the fiber structure of the prostate gland to relax, given these programmed parameters.

Krakovsky'840 does not disclose that the time periods for the first and second pulse trains are on an order of a week. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a training period on the order of a week, since it has been held that, where the general conditions of a claim are disclosed in the prior art, discovering an optimum value or range for a result effective variable involves only routine skill in the art.

It is noted that claim 28 and, by way of dependency, claim 29 invoke the means-plus-function language of 35 U.S.C. 12, 6th paragraph, where the means for generating and delivering a training sequence of stimulation pulses is taken to refer to the device described above comprising one or more leads, one or more pulse generators, and a processor control circuit.

It is noted that the functional language of the device claims does not distinguish the instant application over the Krakovsky'840 device because the earlier patented device is inherently capable of all the limitations contained in the instant claims.

13. Claims 1, 5-11, 18, 30-32, and 38-40 are rejected under 35 U.S.C. 102(e) as anticipated by or Whitehurst'895, in the alternative, under 35 U.S.C. 103(a) as obvious over Whitehurst'895 in view of Whitehurst'294 or in view of Brenman'102.

Regarding claims 1, 5 and 6, Whitehurst'895 discloses a method of delivering one or more therapeutic stimulation pulses via an implantable medical device to treat sexual dysfunction (TITLE; ABSTRACT); wherein the stimulation pulses treat dysfunction by causing erection and ejaculation (column 3, line 64 through column 4, line 6; column 6, lines 44-51).

Regarding claim 2, and further regarding claim 1, it is noted that Whitehurst'895 discloses stimulation of the nerves around the tissue of the prostate (column 1, lines 46-65; column 5, lines 20-38). However, it is commonly accepted in the medical art that stimulation of a muscle is in fact referring to the stimulation of the motor neurons effecting the muscle tissue, as such tissue in and of itself is not capable of producing a cause-and-effect relationship or providing for propagation of an electrical stimulation throughout an entire organ (such as the prostate) or across a significant distance without coincident stimulation of adjacent nerves. Therefore, a stimulation of the nerves proximally located to or affecting the prostate organ, both of which are disclosed in Whitehurst'895, signifies an inherent stimulation of the prostate tissue itself. Therefore, the limitation of the instant claims does not distinguish over the prior art.

Alternatively, in the same field of endeavor, Whitehurst'294 teaches direct electrical stimulation of the prostate to provide a minimally invasive means of reducing prostate volume (column 3, lines 55-68). Additionally, Brenman'102 teaches direct

electrical stimulation of the prostate gland to induce erection (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Whitehurst'895 to include direct electrical stimulation of the prostate gland as taught by Whitehurst'294 in order to provide the same benefit of reducing prostate volume with a minimally invasive process (motivation to combine provided by Whitehurst'294, column 3, lines 55-68) or as taught in Brenman'102 to induce erection.

Regarding claims 7-9, Whitehurst'895 discloses a method preventing ejaculation and premature ejaculation (column 5, lines 34-38; column 17, lines 15-20), given that inhibiting erection would serve to delay or inhibit ejaculation, and that it is stated that a user can turn off the device to return the user to a flaccid state (column 14, lines 66-67).

Regarding claim 10, Whitehurst'895 discloses using telemetry with a patient programmer (columns 14-15).

Regarding claim 11, Whitehurst'895 discloses using sensed physiological conditions (column 4, lines 42-52; column 12, line 64 through column 13, line 17)

Regarding claim 18, Whitehurst'895 discloses delivering drugs to the prostate in conjunction with delivering one or more therapeutic stimulation pulses (column 3, line 64 through column 4, line 30).

Regarding claims 30-32, 38 and 39, Whitehurst'895 discloses an implantable medical device that delivers stimulation pulses to the prostate gland (as outlined above) and an implantable drug pump programmed to deliver stimulation pulses and agents in complementary fashion (column 3, line 63 through column 4, line 51; column 10, lines

60-65). It is noted that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

14. Claims 4, 19-22, 24-25, 27, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst'895 in view of Mann'171; or Whitehurst'895 in view of Whitehurst'294 as applied to claim 1 above, further in view of Mann'171 and still further in view of Krakovsky'840.

Regarding claims 4, 21 and 27, Whitehurst'895 or Whitehurst'895 in view of Whitehurst'294 discloses the method of the present invention substantially as claimed, but does not expressly disclose the parameter limitations of using pulse widths between 180 and 450 microseconds and voltage between 1 and 10 volts. In the same field of endeavor, Mann'171 teaches a pulse width range of 50-350 microseconds and a frequency range of 2-20 pulses per second (Hz) as being typical for electrical stimulation of male reproductive nerves (column 21, line 48 through column 22, line 14).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ these ranges for stimulation parameters in the method of the Whitehurst'895 or Whitehurst'895 in view of Whitehurst'294 to achieve the same advantage of successful and clinically safe control of male sexual function (motivation to combine provided by Mann'171, column 21, line 48 through column 22, line 14).

Regarding claims 19, 20, 22, 24, 25, 28, 29, 33-37, 41 and 42, Whitehurst'895 in view of Mann'171or Whitehurst'895 in view of Whitehurst'294, f.i.v. Mann'171 discloses

the method and device of the present invention substantially as claimed, but does not expressly disclose that the training sequence define a first and second pulse train, wherein the second pulse train includes more pulses per unit time than the first pulse train. In the same field of endeavor, Krakovsky'840 clearly shows in Figs. 12 and 13 a training sequence where a second, third and fourth, pulse sequence each includes more pulses per unit time than the previous sequence for the purpose of treating sexual dysfunction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as disclosed by the combinations of Whitehurst'895, Whitehurst'294 and Mann'171 with a similar pulse sequence structure to provide the system with the same advantages of treating sexual dysfunction (motivation to combine provided by Figs. 12 and 13 of Krakovsky'840).

It is noted that Whitehurst'895 does not disclose that the time periods for the first and second pulse trains are on an order of a week. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a training period on the order of a week, since it has been held that, where the general conditions of a claim are disclosed in the prior art, discovering an optimum value or range for a result effective variable involves only routine skill in the art.

15. Claims 24, 25, 27, 28, 29, 41 and 42 rejected under 35 U.S.C. 103(a) as being obvious over Gerber'240, or over Gerber'240 in view of Krakovsky'840.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome

by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Gerber'240 discloses the invention substantially as claimed (see paragraph 6 above), but does not expressly disclose that the time periods of a first and second pulse train are on the order of one week. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a training period on the order of a week, since it has been held that, where the general conditions of a claim are disclosed in the prior art, discovering an optimum value or range for a result effective variable involves only routine skill in the art, where paragraph [47] of Gerber'240 establishes therapy parameters such as pulse width and therapy duration as result effective variables.

Alternatively, in the same field of endeavor, Krakovsky'840 clearly shows in Figs. 12 and 13a training sequence where a second, third and fourth, pulse sequence each

includes more pulses per unit time than the previous sequence for the purpose of treating sexual dysfunction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as disclosed by Gerber'240 with a similar pulse sequence structure to provide the system with the same advantages of treating sexual dysfunction (motivation to combine provided by Figs. 12 and 13 of Krakovsky'840).

16. Claims 19-22 and 33-37 are rejected under 35 U.S.C. 103(a) as being obvious over Gerber'240 in view of Mann'171; or over Gerber'240 v. Krakovsky'840 and further in view of Mann'171.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Gerber'240 discloses the method of the instant application substantially as claimed except that the therapeutic stimulation pulses be used to train the prostate gland to become more compliant, i.e. relax its fiber structure. In the same field of endeavor, Mann'171 teaches a stimulation of the nerve pathways of the bladder that yields the desired result of diminishing involuntary bladder contractions (i.e. relaxing the fibrous muscle structure of the bladder) and increasing volume of the bladder (i.e. increasing compliance of the bladder wall) (ABSTRACT). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that similar stimulation of the prostate, given its similar physical composition to the bladder and its corollary position in the reproductive system to that of the bladder in the urinary system, could be employed in the method of the Gerber'240 patent to achieve the same results of a relaxing of the fiber structure and increase in compliance of the prostate organ (motivation to combine provided by Mann'171, ABSTRACT). Additional limitations of the rejected claims not discussed explicitly in this paragraph are considered to have been addressed in previous sections of this Action.

Response to Arguments

17. Applicant's arguments filed 21 August 2007 with regard to independent claim 1 have been fully considered but they are not persuasive.

Regarding independent claim 1, Applicant argues that none of the applied references discloses or suggests stimulation of muscle tissue of the prostate gland specifically for treatment of sexual dysfunction and further that any conclusion of obviousness is wrong because benign prostatic hyperplasia (BPH) and sexual dysfunction are different disorders.

In response to applicant's argument that stimulation of the prostatic muscle tissue is not specifically disclosed for treatment of sexual dysfunction, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, the combinations presented herein relying upon the teachings of Whitehurst'294 and Brenman'102, which both clearly disclose stimulation of the prostate gland to treat sexual dysfunction.

In response to applicant's argument that there is no suggestion to combine the references because BPH and sexual dysfunction are different disorders, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21

USPQ2d 1941 (Fed. Cir. 1992). In this case, the fact that BPH is different from sexual dysfunction does not negate the combinability of the references. It is noted that studies previously presented have conclusively and intimately linked BPH and sexual dysfunctions, wherein proper treatment of BPH leads to improved sexual function (e.g. relief of erectile dysfunction) and worsening of the BPH condition contributes to deterioration of sexual faculty including decreased ejaculation volume (Schou et al.); decrease in libido (Carbone et al.); or retrograde ejaculation and discomfort. Therefore, it is considered to be well within the common knowledge of one skilled in the art to understand that a treatment of BPH also has positive effects in treating symptoms of sexual dysfunction which are exacerbated by the BPH condition.

18. Applicant's arguments filed 21 August 2007 with regard to independent claims 19, 24, 28 and 33 have been fully considered but they are not persuasive.

In considering the following, it is noted that claims 24 and 28 are directed to a *device*, whereas claims 19 and 33 are directed to a *method*. Therefore, the Krakovsky reference is sufficient to anticipate the *device* claims since the disclosed apparatus is capable of performing all intended functionality of the claimed invention and includes all of the structural limitations set forth in the instant device claims.

Regarding Applicant's argument that claims 19, 24, 28 and 33 are not concerned with treatment of sexual dysfunction but rather provide for training pulses to the prostate gland for treatment of BHP, it is noted that the claims as written are not specific as to the pathology of the treated disease, and therefore the fact that the applied reference is

for treatment of sexual dysfunction does not preclude the art from anticipating the claims.

Regarding Applicant's various arguments that Krakovsky and Whitehurst'294 fail to teach delivery of a training sequence of pulses, it is noted that such a training sequence is clearly and explicitly disclosed in the cited paragraphs and figures of Krakovsky as reiterated above for emphasis from the previous Office Actions. Specifically looking at Figures 12 and 13 of Krakovsky, Examiner fails to comprehend how a pulse train or training sequence as claimed by Applicant can be reasonably distinguished from stimulation delivered at a first frequency delivered for a specific time immediately followed by stimulation of a second frequency for a second specific time as is clearly depicted, and which is very obviously different from an individual stimulation.

Regarding Applicant's argument that the limitation of delivering stimulation over the period of a week does not constitute a results-effective variable, it has been firmly established in the case law that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art. Krakovsky'840 clearly establishes that the time period of stimulus delivery is a result effective variable in column 3, lines 36-46 as previously cited. These lines state that any of pulse height, pulse width, frequency, duration and sequence can be reprogrammed for each individual patient, where the best program for each patient is best determined by testing.

19. Applicant's arguments filed 21 August 2007 with respect to claims 30 and 38 have been fully considered but they are not persuasive.

20. In response to applicant's argument that the applied references do not explicitly teach implanting electrodes on or within the muscle tissue of the prostate gland or additionally delivering agents thereto in a complementary or otherwise fashion, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the devices of all the applied references are capable of use on or in the prostatic muscle tissue, and therefore read on the device claims as presented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Christopher A. Flory

30 August 2007

/George Manuel/
Primary Examiner